



VIRGINIA COMMONWEALTH UNIVERSITY
**Human Research
Protection Program**

NEWSLETTER

HRPP Transformation Project

The HRPP is thrilled to announce a significant leap forward in our commitment to protecting human research participants through the HRPP Transformation powered by the Huron Consulting Toolkit. This transformative initiative introduces new policies, procedures, work instructions, and an investigator's guide, reinforcing our dedication to excellence in research ethics and participant safety.

Key Components of the HRPP Transformation:

New Policies and Procedures

Our HRPP now boasts a comprehensive set of updated human research protection program plan, policies, and procedures aligned with the latest industry standards. These changes are designed to streamline processes, enhance clarity, and ensure the highest level of ethical conduct in human research.

Investigator's Guide

The introduction of an investigator's guide equips researchers with a valuable resource to navigate the complexities of the research process. This guide serves

as a roadmap, providing step-by-step instructions and best practices to promote adherence to ethical standards and regulatory compliance.

Check out the recently updated [HRPP Transformation Project](#) web page for more information!

****If you receive an error message from the hyperlinks, please copy/paste the address into your browser.*

HRPP Toolkit Go-Live and Updates

The [HRPP Toolkit](#) has successfully been in active operation since *July 14, 2023*. This comprehensive toolkit comprises workflows, standard operating procedures, checklists, worksheets, and templates meticulously crafted to adeptly handle IRB submissions throughout the study lifecycle. Protocol and consent templates are included in the toolkit and have been designed to align, and emerge, with institutional expectations and industry standards.

We are committed to continuous improvement, actively refining and expanding the toolkit's elements. For a detailed overview of the HRPP toolkit components, please refer to the [HRPP Toolkit Overview Deck](#).

****It is important to note that the previous VCU HRPP WPPs are now obsolete, and we are in the process of systematically replacing them with the new and enhanced HRPP Toolkit wherever applicable.*

HRPP Training for the Research Community

*****SAVE THE DATE*****

HRPP Annual Conference

October 24, 2024

Mark your calendars and save the date for an exciting event you won't want to miss!

The Human Research Protection Program (HRPP) is thrilled to announce the upcoming VCU HRPP Conference: "Ensuring Ethical Excellence in Human Studies Research Compliance"

Hosted by the Human Research Protection Program at Virginia Commonwealth University, this conference promises to be an invaluable opportunity for researchers, ethicists, compliance professionals, and all stakeholders involved in human studies research.

Join us as we delve into critical topics surrounding ethical excellence in human studies research compliance. From best practices to emerging trends, our lineup of speakers and sessions will provide insight, inspiration, and practical guidance to enhance your work in this vital field.

Date: Thursday, October 24, 2024

Time: 9:00 am est- 4:00 pm est

Location: Virtual Event via Zoom

Registration link will be released at a later time

*****Conference Keynote speaker announced*****



Brie Haupt, PhD

In January 2024, Dr. Haupt was a featured guest on VCU CompassPoint podcast titled Finding support and success when

Brittany “Brie” Haupt, Ph.D., is an Assistant Professor at Virginia Commonwealth University in the Homeland Security & Emergency Preparedness Department. She is an expert in crisis communication, cultural competency, and emergency and crisis management. In 2021, Haupt's book, with Dr. Claire Connolly Knox, on *Cultural Competence for Emergency and Crisis Management: Concepts, Theories, and Case Studies* won the Book of the Year Award from the American Society of Public Administration's Section on Democracy and Social Justice. This text has been utilized by numerous emergency management programs and incorporated into the Federal Emergency Management Agency's training programs. In 2022, Haupt published a textbook on *Crisis Communication Planning and Strategies for Nonprofit Leaders* with Dr. Lauren Azevedo. This text won the Network of Schools of

navigating the IRB

and shared insights into VCU's IRB process, common challenges and questions that students and faculty may have, and information on how to seek support from a Protocol Navigator Consultant (PNC) as you prepare your submission.

Public Policy, Affairs and Administration's Outstanding Scholarship of Teaching and Learning award sponsored by the Journal of Public Affairs Education. Haupt has been sought out for her expertise and was even invited by Canada-Coalition for Police Reform to speak on Communicating during Crises: Strategies for Community Relations.

Haupt has also published in several peer-reviewed journals (i.e., Public Administration Review, Journal of Public Affairs Education, Disaster Prevention and Management, Risk, Hazards, and Crisis in Public Policy, Natural Hazards Review, Journal of Homeland Security and Emergency Management, Journal of Emergency Management, Frontiers in Communication section on Disaster communications and more). She also serves as a board member for the American Society of Public Administration's Section on Emergency and Crisis Management, co-chair for the Network of Schools of Public Policy, Affairs and Administration's Section on Emergency Management and Homeland Security Programs, a board member for Public Administration Theory Network, a committee member for the NASPAA's Diversity, Equity and Inclusion committee, an associate editor for Natural Hazards Review and associate editor for Frontiers-Disaster Communications.

Stay tuned for further details regarding conference speakers, agenda, and registration information. We look forward to your participation in this important event as we strive to uphold the highest standards of research ethics and compliance.

Together, let's ensure ethical excellence in human studies research. Save the date and be part of the conversation on October 24, 2024!

Additional details will be released over the coming weeks through the HRPP blog and newsletter.

Upcoming Human Subjects Research Events and Trainings

[VCU and Other Local Events](#)

[VCU OVPRI Research Events](#)

National Events

June 24, 2024

What to Know About Conducting Research with HeLa Cells

July 12, 2024

OHRP 50th Anniversary of the National Research Act

September 9 and 10, 2024

OHRP Research Community Forum

September 16-18, 2024

NIJ Annual Conference: Advancing justice through science

Tools to Assist the Research Community with IRB Submissions

As part of the *HRPP Transformation Project*, we created a collection of training sessions designed to ease the community into changes made within the HRPP. Training topics include: review of the HRPP Toolkit, reportable new information, single and multi-site research, vulnerable populations, informed consent, clinical drug and device considerations, and minimal risk research considerations.

Recordings and slides of past sessions are available on the [HRPP Blog](#) and [VCU HRPP/IRB Kaltura channel](#).

Updates to HRPP web content

The HRPP and OVPRI staff have collaborated with external consultants to provide the research community with the most robust and transparent resources for human subjects research, and this included review of the current HRPP web content. The HRPP manages several web pages that provide support for human subjects research at VCU. Revisions to the webpages will be posted as they become available over the next few months and a full transformation for the OVPRI's website is planned for 2024!

Check out the most recent web page updates we have rolled out...

[HRPP Transformation Project](#)

Includes matrix outlining review pathway/fee applicability

HRPP Toolkit

Spotlight Documents

Introducing...

***Check out the fillable HRP protocol docs that were recently posted to the *HRPP Toolkit* and *HRPP Forms webpages!*

[HRP-503 TEMPLATE PROTOCOL](#)

[HRP-503a - TEMPLATE SBS PROTOCOL](#)

[HRP-508 - TEMPLATE Site supplement to sponsor protocol](#)

The HRPP Toolkit documents are updated periodically and updated versions can be found under the [HRPP Toolkit](#) and [VCU HRPP/IRB Forms web pages](#).

Reminders...

- Researchers who plan to separate from VCU must close or amend studies prior to separation. Refer to the [HRPP blogpost for IRB Requirements for Separating PIs](#).
- Research teams must assure the aims and procedures specified in the human research protocol are scientifically sound and justified. This includes clear objectives, background, setting, procedures, data and safety monitoring (if applicable), risks, potential benefits and alternatives to participation.
- The human research protocol and consent information must be consistent with one another for final approval by the IRB. All plans related to selection of subjects, recruitment, research procedures, data collection, data sharing and data dissemination must be clear and consistent across the protocol, consent and other supporting documents.

Institutional resources for human research protocol development and other research support for health studies, any research being conducted on the medical campus, clinical trials and patient centered studies include:

C. Kenneth and Dianne Wright Center for Clinical and Translational
Research

VCU ONETRAC/PROCS

Massey Comprehensive Cancer Center Clinical Trials Office

The Protocol Navigator Consultant (PNC) project provides research support to the academic campus and is designed as a collaboration between the VCU HRPP and several participating academic departments. Current collaborating departments include VCU's School of the Arts, School of Education, College of Humanities and Sciences, the Wilder School, and the School of Social Work. The [Protocol Navigator Consultant \(PNC\) project](#) is considered a primary human research resource for the specified participating academic schools.

The HRPP Toolkit documents will be updated periodically and updated versions will be posted under the [HRPP Toolkit](#) and [VCU HRPP/IRB Forms](#) web pages.

*****HRPP SPOTLIGHT*****

May was...

Mental Health Awareness Month

Jewish American Heritage Month

June is...

PRIDE Month

As a matter of Human Rights and Research Ethics we must strongly consider the manner and purpose for the selection of human participants in research, the minimization of risks and undue burden to individuals and their community/s, and an individual's autonomy over their agreement to participate or have their data or other materials used in research...

There are (3) basic ethical considerations for human subjects research that are outlined under the Belmont report; respect for persons, beneficence, and justice. These principles speak to the autonomy of participants, minimization and balancing of risks/benefits, and fairness in the selection of subjects.

Click on each topic/article that is hyperlinked below to learn more.

****Columns are not organized in any particular order.*

Respect for Persons	Beneficence	Justice
National Institute on Mental Health (NIMH): Human Research Subjects Issues	Centers for Disease Control (CDC) Children's Mental Health Research	U.S. Watchdog Halts Studies at N.Y. Psychiatric Center After a Subject's Suicide - NY Times
American Psychological Association (APA): Human Research Protections	2024 Equity Assessment and Action Steps for Mental Health Compensation Benefits - Department of Veteran Affairs	Anti-Semitism and Jewish views on discrimination - Pew Research Center
Antisemitism Behind the Numbers: Four Stories About What It's Like to Be Jewish in America in 2023 - American Jewish Community	Jewish Students Describe Facing Antisemitism on Campus to Members of Congress	Nuremberg Trials - The National WWII Museum New Orleans
The Nuremberg Code - US DHHS Office of Research Integrity (ORI; 1947)	World Medical Association Declaration of Geneva (1948)	VCU School of World Studies - Judaic Studies

The Declaration of Helsinki was developed ~1964 with consideration of the ethical principles outlined in both the Nuremberg Code and Declaration of Geneva and is centered on medical research. Whereas, the Nuremberg code is written more broadly in terms of its applicability for During the Nuremberg trials it was particularly noted that ethical principles must be strongly applied to non-therapeutic experimentation because risks may outweigh the prospect of benefit to the individual participant or where there may be unknown risk of harm.

LGBTQIA+ and Human Research

Click on each topic/article that is hyperlinked below to learn more.

LGBTQIA+ Equity in Human Subjects Research Review: Acknowledging the Whole Research Participant - PRIM&R	LGBT Populations: A Snapshot of the Knowledge Base and Research Needs - HHS.gov	Research LGBTQ+ by Subject - Library of Congress

<p>Considerations for Advancing LGBTQIA+ Equity in Research - Scholastica.com</p>	<p>LGBTQ-Inclusive Curriculum as a Path to Better Public Health - American Bar Association</p>	<p>Protecting the Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTQI+) People - HHS</p>
<p>Honoring PRIDE Month - Association of Clinical Research Professionals (ACRP)</p>	<p>Research Roundup: Research With Pride: LGBTQIA+ Representation in All of Us</p>	<p><u>VCU Library Research Guides</u></p> <p>LGBTQIA+ Health</p> <p>Transgender Health</p> <p>Intersex Health</p>

Some federal investigations that speak to human research ethics and are currently on the radar...

[Reproductive rights in America - NPR.org](#)

***Update: Final opinion from SCOTUS expected by this summer. See all final opinions issued by SCOTUS over the years [here](#).

[American Academy of Dental Sleep Medicine Special Update: AGGA Investigation](#)

***Update: Seems to have resulted in many class action lawsuits to date, with the inventor and other practitioners who prescribed the dental device levied under extensive scrutiny for the lack of a scientific process being used in the design and implementation of the medical device and apparent failure to obtain FDA oversight for use of the experimental medical device. Professional organizations have posted comments voicing ethics concerns, as the medical device that was implemented may have caused undue harm to patients and appears to have been used without sufficient scientific support and without sufficient oversight to protect participants from potential harms.

[The Patient First Podcast Episode 94: Just How Bad Is the "AGGA" Issue?](#)

[International Association for Dental, Oral, and Craniofacial Research Code of Ethics](#)

Did you know that the National Institutes of Health (NIH) has a center that is specifically dedicated to providing resources to research communities that are centered around research ethics and integrity? Check it out...

Federal and State Human Research Resources

<p>US Department of Health and Human Services (HHS)</p> <p><u>Human Research Protection Program Resources</u></p>	<p>National Institutes of Health (NIH)</p> <p><u>Human Subjects</u></p>	<p>Food and Drug Administration (FDA)</p> <p><u>FDA Meetings, Conferences, and Workshops</u></p>
<p>Department of Defense (DoD)</p> <p><u>DoD Instruction</u></p> <p><u>DOHRP</u></p>	<p>National Science Foundation (NSF)</p> <p><u>Research Involving Human Subjects</u></p>	<p>Environmental Protection Agency (EPA)</p> <p><u>Human Subjects Research</u></p>
<p>World Health Organization (WHO)</p> <p><u>Ethical Standards for Research with Human Beings</u></p>	<p>Department of Veterans Affairs (VA)</p> <p><u>VA HRPP</u></p>	<p>National Institutes of Justice (NIJ)</p> <p><u>Human Subjects and Privacy Protections</u></p>
<p>Indian Health Service (IHS)</p> <p><u>Tribal Governance and Human Subjects Research</u></p>	<p>United States Federal Register</p> <p><u>Federal policy for the protection of human subjects in research</u></p>	<p>Virginia State Code</p> <p><u>Human Subjects Research</u></p> <p>Virginia Department of Social Services (VDSS)</p> <p><u>VDSS IRB</u></p>

If you would like your research featured in one of our upcoming newsletters, please submit a request.

[Submit a newsletter request](#)

Disclaimer

The views and opinions expressed in this media do not necessarily reflect the official policy or position of Virginia Commonwealth University (VCU) or the Human Research Protection Program (HRPP). The content provided is for informational purposes only and should not be construed as

legal or professional advice. Any references to specific products, services, or organizations do not constitute an endorsement or recommendation by VCU or HRPP.

VCU Human Research Protection Program | Box 980568 | Richmond, VA 23298 US

[Unsubscribe](#) | [Update Profile](#) | [Constant Contact Data Notice](#)



Try email marketing for free today!